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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/826,731

04/05/2001

Jerome Owen Cantor

8515

7590

07/03/2002

Bronislava Shteyngart MD  
242 92nd Street  
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EXAMINER
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MELLER, MICHAEL V

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 07/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/826,731

Applicant(s)

CANTOR ET AL.

Examiner

Michael V. Meller

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.

1) ☐ Notice of Entry of the Application

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_

4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: \_\_\_\_\_

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**DETAILED ACTION**

***Election/Restrictions***

The election of species is noted and remains proper. Applicants elected pneumonia as the disorder to be treated.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 102***

Claims 1, 5, 13, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Gavrilenko et al. for the reasons of record and for the reasons which follow.

Applicant argues that Gavrilenko teaches using the lysozyme to treat chronic bronchitis which is a disease of the upper airways and not the lung. Gavrilenko uses the same composition and administers it in the same way as applicants. The composition of Gavrilenko will inherently treat the lung since the same composition is being administered in the same way as applicants have done.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Kats et

For the above reasons with regard to Gavrilenko, those comments are also pertinent to Kats.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhorov et al. for the reasons of record and for the reasons which follow.

For the above reasons with regard to Gavrilenko, those comments are also pertinent to Zhorov.

### ***Claim Rejections - 35 USC § 103***

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vyrenkov et al. taken with Gavrilenko et al., Zhorov et al. and Kats et al. for the reasons of record and for the reasons which follow.

Applicants argue that Vyrenkov teaches administration of the lysozyme endolymphatically and that this would be superior to intratracheal administration. They further argue that since administering the enzyme endolymphatically would be superior to intratracheally that this is a teaching away.

The fact of the matter is drugs are administered in many different ways. Some are administered orally, systemically, etc. It is the choice of the artisan to administer the drug in one of many different ways. It clearly would have been within the purview of the

intratracheally instead of endolymphatically since it is merely the choice of the artisan to employ different methods of administration of a drug. Further, it would have motivated one to administer the drug (lysozyme) intratracheally since this is a common method for treating the lung. To administer a compound by nebulization is well known in the art and is commonly used by the skilled artisan as is the case with inhalers. Further, the secondary references make it clear that administering the lysozyme intratracheally is highly desirable and clearly within the purview of the skilled artisan.

The comments concerning the claimed dosage range are noted, the examiner agrees that this range is appropriate and well known in the art considering the differences in weight between neonates and adults as stated by applicant in applicants last response, paper numbers 7 and 9.

An examination of this application reveals that applicant is unfamiliar with patent prosecuting procedure. While an inventor may prosecute the application, lack of skill in this field usually acts as a liability in affording the maximum protection for the invention disclosed. Applicant is advised to secure the services of a registered patent attorney or agent to prosecute the application, since the value of a patent is largely dependent upon skillful preparation and prosecution. The Office cannot aid in selecting an attorney or agent.

Applicant is advised of the availability of the publication "Attorneys and Agents Registered to Practice Before the U.S. Patent and Trademark Office." This publication

is for sale by the Superintendent of Documents, U.S. Government Printing Office,  
Washington, D.C. 20402.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 703-308-4230. The examiner can normally be reached on Monday thru Friday: 9:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-0294 for After Final

Application/Control Number:  
09/826,731  
Art Unit: 1651

Page 6

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Michael V. Meller  
Examiner  
Art Unit 1651

MVM  
June 24, 2002